

REMARKS

Claims 1-7, 9-14, 19-21, 15-18, 23 and 25 are now in the application. Claims 15 and 18 have been amended to recite “an ordinary food enriched with ubiquinone”. Support for the amendment to Claims 15 and 18 can be found for example on page 1, lines 6 to 12 in the specification. Claim 23 has been amended to correct a typographical error for purposes of clarity and not to limit its scope. Newly added Claim 25 is supported at page 3, lines 14 to in the specification. The amendments to the claims and newly presented claim do not introduce any new matter. Claims 15-18 and 23 are drawn to the elected invention. Claims 1-7, 9-14 and 19-21 are drawn to non-elected invention and may be cancelled by the examiner upon the allowance of the claims directed to the elected invention.

Before addressing the rejections of the claims over the cited art, a discussion of the present invention would be helpful. In particular, the present invention is directed to a process for producing ordinary food enriched with ubiquinone which comprises dissolving ubiquinone in an oil/fat under heating at a heating temperature of not lower than the melting point of ubiquinone, and adding the obtained mixture to a food material.

Ubiquinone is a substance indispensable for maintaining biological functions, but the ubiquinone content in the body decreases markedly due to aging and various stresses to which the living body is subjected. In order to supplement ubiquinone, people usually take a supplement in the form of tablets or capsules. In this case it is necessary to purposely take a supplement apart from ordinary foods.

Ordinary food enriched with ubiquinone enables the taking of ubiquinone more easily and conveniently. According to the present invention, it is not necessary to purposely take a supplement in the form of tablets or capsules apart from the ordinary foods in order to supplement sufficient amount of ubiquinone. However, it is necessary to add a large amount of ubiquinone to food materials in the preparation process of foods since the ubiquinone content in ordinary foods is very low.

When a large amount of ubiquinone is added to food materials, there arise serious problems of separation or localization of ubiquinone, which adversely affects flavor, texture and appearance of the foods. If ubiquinone localizes in the food, for example, the food partially shows yellow color which is the color of ubiquinone.

In case of supplements in the form of capsules or tablets, it is only necessary to simply encapsulate a large amount of ubiquinone in capsules or tablets since uniformity (with regard to the appearance and flavor) is not a critical issue.

The present invention is concerned with solving the problems of separation or localization and makes it possible to provide an ordinary food enriched with ubiquinone that exhibits excellent flavor, texture and appearance. The ubiquinone-enriched food can be produced by adding a composition containing ubiquinone and an oil/fat to a food material in the manufacturing process. However, the solubility of ubiquinone in oils/fats is remarkably low at room temperature (please see page 6, lines 3 to 10 of the specification). In order to add a large amount of ubiquinone to an oil/fat, ubiquinone is completely dissolved in an oil/fat under heating at a heating temperature of not lower than the melting point of ubiquinone. This process enables the addition of ubiquinone over its solubility limit in the oil/fat.

Claims 15-16, 18 and 23-24 were rejected under 35 USC §103 over US Patent 6,616,942 to Udel in view of US Patent 4,049,831 to Ono. The cited references do not render obvious the present invention.

Udel relates to the production of soft gel capsule formulation. Soft gel capsules are distinct from ordinary foods according to the present invention. Therefore, those skilled in the art would not recognize from Udel the problem of separation or localization of ubiquinone in foods.

Udel suggests a method of producing a soft gel capsule comprising heating rice bran oil to 50 to 60°C, adding bee's wax and mixing them together to obtain a uniform mixture, cooling the mixture to 35 to 45°C, adding coenzyme Q₁₀, MCT (medium-chain triglycerides) and other

components and mixing together, cooling the resultant mixture to 25 to 30°C and encapsulating it in a soft gel capsule (please see col. 3, lines 7 to 45).

The solubility of ubiquinone in oils/fats is remarkably low at room temperature (page 6, lines 3 to 10 of the specification). According to the present invention, in order to add a large amount of ubiquinone to an oil/fat, ubiquinone is completely dissolved in an oil/fat under heating at a heating temperature of not lower than the melting point of ubiquinone. Heating increases solubility of ubiquinone, and enables the addition of ubiquinone over its solubility limit in the oil/fat. Further, ubiquinone is uniformly dispersed in foods, so that the ordinary foods have favorable texture and appearance of the foods.

As appreciated by the Examiner, Udel fails to teach dissolving ubiquinone in an oil/fat under heating at a temperature of not lower than the melting point (about 48°C) of ubiquinone. According to the Final Office Action, it would have been obvious to add ubiquinone as a heated liquid above its melting point in order to provide a uniformly distributed ubiquinone product. Udel clearly suggests adding coenzyme Q₁₀ to the mixture of oil and bee's wax at a temperature of 35 to 45°C, that is lower than the melting point of ubiquinone. Udel suggests that it is unnecessary to dissolve ubiquinone under heating at a heating temperature of not lower than the melting point of ubiquinone, since Udel aims to provide supplements, in which there is no problem of separation or localization of ubiquinone.

According to Udel, rice bran oil is once heated to 50 to 60°C and bee's wax is added, but the mixture is purposely cooled to 35 to 45°C and then ubiquinone is added with other components. Therefore, there is no motivation to add ubiquinone under heating at a temperature of not lower than the melting point (about 48°C) of ubiquinone. To do so would be contrary to the suggestions of Udel.

As mentioned above, Udel relates to a production of soft gel capsule formulation and soft gel capsules are distinct from ordinary foods according to the present invention. Therefore, the suggestions of Udel do not belong to the field of foods and those skilled in the art would not recognize the problem of separation or localization of ubiquinone in foods. As discussed above,

the problem addressed by the present invention is not a problem of concern with soft gel capsules.

Furthermore, as mentioned in the Advisory Action, the bee's wax of Udel helps to provide uniformity. This comment in the Advisory Action supports the fact that the bee's wax is used as a suspension agent for enabling uniformity of the composition and it is not necessary to heat and dissolve ubiquinone uniformly in oils/fats. Also, please see col. 3, lines 12 to 13 and col. 3, lines 36 to 38 of Udel. Accordingly, the present invention (claim 15) is not at all obvious from Udel.

Regarding claim 16, it is important to note that MCT used in Udel is not a solid fat.

The attached reference (Sasol, Product Information, MIGLYOL® 810, 812, 818, 829 and 840) shows product information of Miglyol 812, that is the MCT used in Udel (it seems apparent that "Miglyol" in Udel is a typographical error). The attached reference teaches that Miglyol is liquid at 0°C (page 1), and cloud point (synonymous with melting point) of Miglyol 812 is lower than 10°C (page 2). It is clear that the MCT used in Udel is a liquid at 20°C.

In addition, as pointed out in our prior response, it is known that MCT is obtained by fractionation of low melting point fraction, namely liquid oil, of coconut oil. Ferencikova et al., Physiol. Res. 52: 73-38, 2003; (hereinafter Reference 1), submitted with our prior response teaches the composition of Miglyol 812 used in Udel (page 74, lines 11 to 14). According to Reference 1, Miglyol 812 is a mixture of triglycerides containing C₆-C₁₂ fatty acids as the constituent fatty acids. Specifically, C₈ fatty acid (caprylic acid) and C₁₀ fatty acid (capric acid) account for more than 80% of the fatty acids which constitute the triglycerides while lauric acid accounts for 5% at most. Accordingly, in view of the reference submitted with this response and Reference 1, it is clear that the melting point of MCT is not 20°C or higher.

Accordingly, Udel is silent about dissolving ubiquinone under heating in a solid fat having a melting point of not lower than 20°C.

Ono uses hydrogenated coconut oil having a melting point of 38°C. According to the Office Action, the melting point of triglycerides can be higher or lower depending on the degree of hydrogenation (please see page 5, first paragraph). However, the Examiner's attention is kindly directed to the Akpan et al. Pakistan Journal of Nutrition 5 (2): 106-109, 2006 (hereinafter Reference 2); previously submitted. Reference 2 discloses the fatty acid profile of various coconuts (Table 2). Medium chain fatty acids constituting coconut oils are caproic acid, caprylic acid, capric acid and lauric acid, which are all saturated fatty acids. Therefore the MCT fraction of coconut oil is not hydrogenated and the melting point of MCT does not change by hydrogenation.

According to Table 2 of Reference 2, coconut oils are composed of C₆-C₂₀ fatty acids, lauric acid accounting for about 38-45% and C₆-C₁₂ fatty acids accounting for about 60% in total. Meanwhile, fatty acids other than medium chain fatty acids, i.e. myristic acid, palmitic acid, stearic acid, arachidonic acid, oleic acid and linoleic acid, account for about 40%. The melting point of coconut oil increases by hydrogenation because C=C bonds of unsaturated long chain fatty acids such as arachidonic acid, oleic acid and linoleic acid are hydrogenated, so that arachidic acid and stearic acid and the like are produced. This is common knowledge to those skilled in the art.

As discussed above it is inappropriate to interpret the teaching of Ono as a teaching that the melting point of MCT increases by hydrogenation. Accordingly, those skilled in the art would not be motivated from the teachings of Udel and Ono to use a solid fat. The attached references are being presented in this response to address comments made in the Final Office Action and therefore were not presented earlier.

Claims 15-18 and 23-24 were rejected under 35 USC §103 as US patent application publication 2003/0113307 to Selzer in view of Udel and Ono. The cited references do not render obvious the present invention. The above discussions of Udel and Ono are incorporated herein by reference.

As appreciated by the Examiner, Selzer fails to teach dissolving ubiquinone in an oil/fat under heating at a temperature of not lower than the melting point (about 48°C) of ubiquinone. Selzer merely suggests mixing an oil phase containing coenzyme Q₁₀ and oil.

Further, Selzer teaches that coenzyme Q₁₀ is not very stable and deteriorates at temperatures above 115°F, namely 46°C (paragraph [0006]). The Examiner mentions in the Advisory Action that the above statement at paragraph [0006] of Selzer means that precautions should be taken when handling. This comment further supports the fact that those skilled in the art would take precautions when handling ubiquinone and, without any specific reason, would not be motivated to heat ubiquinone at temperatures above 115°F. Accordingly, Selzer teaches away from dissolving ubiquinone in an oil/fat under heating at a heating temperature of not lower than the melting point of ubiquinone.

In addition, the composition according to Selzer is used as a dietary supplement and/or therapeutic supplement. The suggestions of Selzer do not belong to the field of ordinary foods according to the present invention. Therefore, those skilled in the art would not recognize from the teachings of Selzer for solving the problem of separation or localization of ubiquinone in foods.

According to the present invention, on the other hand, ubiquinone is dissolved in an oil/fat under heating at a temperature of not lower than the melting point (about 48°C) of ubiquinone. Ubiquinone is dissolved purposely at high temperatures in order to prevent separation or localization of ubiquinone in ordinary foods.

As discussed above, neither Udel nor Ono suggest dissolving ubiquinone in an oil/fat under heating at a temperature of not lower than the melting point (about 48°C) of ubiquinone. Selzer does not remedy the deficiencies of Udel and Ono. Accordingly, the present invention is not rendered obvious even if these references are combined.

Therefore, to modify the cited references by heating at a temperature of not lower than the melting point (about 48°C) of ubiquinone would be contrary to their disclosures. It is improper to disregard teachings that lead away from the invention in evaluating non-

obviousness. All of the teachings in the art must be considered including those that teach away. Please see *In re Mercier* 185 USPQ 774 (CCPA, 1975). Moreover, where, as here, the teachings of the prior art would discourage persons skilled in the art from doing what applicant teaches and claims, the art establishes the “very antithesis of obviousness”. Please see, *In re Rosenberger*, 156 USPQ 24 (CCPA, 1967) and *In re Buehler*, 185 USPQ 781 (CCPA, 1975).

In view of the above, consideration and allowance are respectfully solicited.

In the event the Examiner believes an interview might serve in any way to advance the prosecution of this application, the undersigned is available at the telephone number noted below.

The Office is authorized to charge any necessary fees to Deposit Account No. 22-0185, under Order No. 21581-00488-US from which the undersigned is authorized to draw.

Dated: September 9, 2009

Respectfully submitted,

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